RESEARCH ON METHODS – Study Design

PRMS1

COMPREHENSIVE REVIEW OF EMPLOYER-SPONSORED WELLNESS STRATEGIES AND THEIR ECONOMIC AND HEALTH-RELATED OUTCOMES: EVIDENCE QUALITY AND OPPORTUNITIES FOR FUTURE RESEARCH

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OBJECTIVES: A rising number of companies are sponsoring wellness programs to improve employee health and reduce health care costs. This review sought to determine the characteristics and outcomes of employer-sponsored wellness programs and determine possible reasons for their success. METHODS: PubMed, ABI Inform, Business Source Premier, and Corporate Wellness Magazine were searched. English-language articles published from 2005–2011 reporting characteristics of employer-sponsored wellness programs and their impact on health-related and economic outcomes among US employees were accepted. Animal studies, non-US-based studies, editorials, and economic models were not accepted. Data were abstracted, synthesized, and interpreted. RESULTS: Twenty references were accepted. Wellness interventions were classified into health assessments, lifestyle management, and behavioral health. While improved economic outcomes were reported for companies with wellness programs (ie, total health care costs, return on investment, absenteeism, productivity, workers’ compensation, utilization) as well as decreased health risks, cause-and-effect relationships could not be determined. Fourteen accepted articles were published in magazines and four in newspapers. Only three were published in peer-reviewed journals and those articles were the only ones to report a study design: 2 were described as quasi-experimental and the third a survey. Most articles described the company’s wellness programs and outcomes, with some reporting changes over time. Some of the reported wellness programs were not described in full detail. Many types of outcomes were described across accepted articles, which precluded comparisons of an individual outcome across studies. Some articles described multiple interventions, making it difficult to assess benefits from individual interventions. CONCLUSIONS: While employer-sponsored wellness programs are being reported along with improved outcomes, there are limited definable data on a cause-and-effect relationship. Further research, of a high methodological caliper, is needed to support informed decisions. Specifically, randomized trials and economic analyses would empower employers with the information needed to implement successful wellness programs.

PRMS2

SYSTEMATIC REVIEW OF GUIDELINE RECOMMENDATIONS ON COMPARATOR SELECTION IN HEALTH ECONOMIC EVALUATIONS

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OBJECTIVES: Choice of comparator(s) is a critical design parameter for any health economic evaluation (HE). HE guidelines may differ in their recommendations on comparator selection. Lack of specific regulatory requirements or guidances for source data verification (SDV) in these studies, however, leaves sponsors and partner CROs to determine the level of SDV applied. If multiple publications referred to a single study or registry, only one representative publication was selected for inclusion. RESULTS: Of the observational studies included, 37 studies mentioned SDV in their methods section. Of these, 16 (43%) did not further specify the level of SDV in the remaining 21 studies. SDV ranged from 0 to 100%, with a median of 10%. Subject numbers in these 21 studies ranged between 135 and 19,870, median (864.) These studies were mainly prospective (14/21) and were conducted in the EU (16/21), China (1/21), Australia (1/21), the Philippines (1/21) and worldwide (2/21). The majority (10/11) of the studies were reported to be funded by the pharmaceutical industry. Generally, studies larger than 1,000 subjects sought to verify data sources for only 10% of their population. CONCLUSIONS: The level of SDV is not routinely specified in the methods section of observational study publications. In those publications that did elaborate on methodological quality, the level of SDV ranges from 0% and 100%, with large (n>1000 subjects) observational studies restricting the level of SDV to a maximum of 10%.

PRMS4

A CONCEPTUAL ANALYSIS OF WHEN MEDICAL EXPENDITURE PANEL SURVEY (MEPS) MEETS COST OF ILLNESS (COI) – ARE THEY A MATCH?

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OBJECTIVE: MEPS has been used as a data source for many direct medical expenditures (DME)/COI type studies. The objective of this conceptual analysis is to review the literature & evaluate the 4 main COI type studies with reference to patients with head and neck cancer (HNC) using the MEPS data source. METHODS: The literature was retrieved from PubMed (nr 8). Results and discussion was split into 4 main methods approaches: 1) Matched Control, 2) Regression, 3) Matched Control or Regression. Without a comparison group, analysts use a total cost approach. With a comparison group, an incremental cost approach is more often reported. ISPOR does not have standard guidelines in reporting COI studies; analysts often vary in their perspective, but should always make reference to medical costs, morbidity & mortality costs, transportation/nonmedical costs and productivity losses in their analysis. RESULTS: A review of recent COI type papers (n=10) that have used MEPS shows that analysts report findings based on usually 1 COI method. Only 2 studies (COPD & Diabetes) reported both total and incremental cost approaches in their analysis. Four studies merged condition, event and consolidation of years, which allows diagnosis specific estimates to be produced. As a conceptual analysis, HNC is used to illustrate that MEPS facilitates analysts to use the main COI methods especially if DME is the outcome of interest. CONCLUSIONS: MEPS is a valuable and utilized national resource. It is possible that “good practice guidelines” can be developed (perhaps endorsed by AHRQ) for those using MEPS to report a DME/COI type study. By using & reporting all 4 methods, an analyst is giving policy-makers a range for their cost estimates. Guidelines would ensure a level of transparency in reporting such cost estimates across conditions.

PRMS5

MODELING THE PROGRESSION OF CHRONIC DISEASES IN A DYNAMIC MARKET: IMPLICATIONS FOR BUDGET IMPACT ANALYSIS

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The ISPOR task force guidelines on good research practices for Budget Impact Analyses (BIA) identify two simultaneous processes affecting the marketplace: changes in the target population resulting from various disease characteristics and changes over time and thus medical costs vary across disease cohorts. Hence, in a budget impact model two constraints must be met: 1) the number of patients progressing from one year to the next corresponds to known disease statistics (i.e., patients who enter the model cannot be “lost to follow-up”), 2) the total number of treated patients conforms with known population size and projected market shares. The current guidelines lack detail on how to satisfy these two constraints simultaneously in dynamic markets with non-trivial rates of patient attrition from treatment groups. OBJECTIVES: To identify a method that allows researchers to more accurately model the budget impact of new interventions for chronic diseases in dynamic markets. METHODS: We propose a simple adjustment factor which is a function of disease and treatment’s attrition rate in two consecutive years to correct the allocation of patients across disease cohorts such that the two constraints identified above are always met simultaneously. We compare two sets of dynamic vs. dynamic markets and analyze the implications over a time period of five years. RESULTS: We find that adjusting the application factor in dynamic markets reduces the bias in budget impact measures by 15% or more and that correcting for this in even more complex markets would lead to higher bias. Our proposed solution is a simple way of accounting for differential rates of attrition across time periods in a study’s results and apply it to budget impact analyses.

PRMS7

COST-EFFECTIVENESS ANALYSIS IN PERSONALIZED MEDICINE: GENERAL HYPOTHESES AND CORRESPONDING DECISION TREE STRUCTURES FOR SCREENING, DIAGNOSTIC, PREDICTIVE, PROGNOSTIC, SURVEILLANCE, AND MONITORING TESTS

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